Medacta International

MAY 17 2013

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: December 14, 2012

DEVICE INFORMATION

Trade/Proprietary Name: MectaLIF Anterior
Common Name: Anterior Intervertebral Body Fusion Device
Classification Name: intervertebral fusion device with integrated fixation, lumbar

21 CFR 888.3080
Class II
Device Product Codes: OVD

Predicate Devices:

K101310 Vu aPOD, Integra Spine
K073109 Stalif TT, Centinel Spine
K101301 Stalif Midline, Centinel Spine
K110927 MectaLIF, Medacta International
K072253 SynFix-LR, Synthes
K022791 ATB System, Synthes
K071726 Zuma, SeaSpine
K082252 Independence, Globus Medical
K013665 Pyramid plate, Medtronic

Product Description

The MectaLIF Anterior is an anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. MectaLIF Anterior is intended to be used with bone screws provided and requires additional supplementary fixation. MectaLIF Anterior consists of a disc spacer made of PEEK-OPTIMA LT1: Implant Grade Polyetheretherketone (ASTM F 2026) which contains three Tantalum Markers (ISO 13782 / ASTM F 560), bone screws made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136), and a plate made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136). The interior of the disc spacer can be packed with autograft or autologous bone graft. The plate comes in three different designs (Flush, Long, and L5-S1) and is secured to the disc spacer via an interlocking mechanism. The disc spacer and attached plate are secured to the vertebral body with the bone screws. The Flush and Long plates are used with four bone screws while the L5-S1 plate is used with three bone screws.

Indications for Use

The MectaLIF Anterior is an anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The interior of the spacer component of the MectaLIF Anterior can be packed with autograft or autologous bone graft.
DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
The MectaLIF Anterior is a system intended to be used with the integrated bone screws provided and requires additional supplementary fixation such as pedicle screws and rods.
These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).
These patients should be skeletally mature and have had six months of non-operative treatment.

Comparison to Predicate Devices

The indications for use, design features and materials of the MectaLIF Anterior are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the MectaLIF Anterior are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The MectaLIF Anterior was tested per ASTM F2077 and ASTM F2267 using the worst-case device for each of the following tests:

1. Static Axial Compression
2. Dynamic Axial Compression
3. Static Compression-Shear
4. Dynamic Compression-Shear
5. Static Torsion
6. Dynamic Torsion
7. Subsidence
8. Expulsion

The performance testing demonstrated that the MectaLIF Anterior is not worst case compared to predicate data.

Conclusion:
Based on the above information, the MectaLIF Anterior can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medacta International SA
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Mr. Adam Gross
Director of Regulatory, Quality and Compliance
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Letter dated: May 17, 2013

Re: K124034
Trade/Device Name: MectaLIF Anterior
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: April 11, 2013
Received: April 15, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K124034

Device Name: MectaLIF Anterior

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Prescription Use ____x____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K124034